UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,910	12/16/2003	Ru Chih Huang	2240-199065	3871

26694 7590 07/01/2009

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	
MAIL DATE	**DELIVERY MODE**
07/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,910	HUANG ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10,15,18-20 and 32-37* is/are pending in the application.

4a) Of the above claim(s) *34-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-10,15,18-20,32-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-10, 15, 18-20 and 32-37 are presented for examination.

Applicant's Amendment filed April 2, 2009 has been received and entered into the present application.

Claims 9-10, 15, 18-20 and 32-37 remain pending. Claims 34-37 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 9-10, 15, 18-20 and 32-33 remain under examination.

Applicant's arguments, filed April 2, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10, 15 and 18-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al. (U.S. Patent No. 5,541,232; 1996), already of record, for the reasons of record set forth at p.3-7 of the previous Office Action dated October 3, 2008, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Howell et al. only teaches the use of the recited compounds only in combination with an additional chemotherapeutic agent. Applicant alleges

that the sections cited by the Examiner do not describe the use of an NDGA derivative as a sole treatment for leukemia and the recitation of "consisting essentially of" clearly distinguishes the instant claims from that of Howell et al., which Applicant alleges teaches the administration of NDGA and NDGA derivatives in combination with an antineoplastic agent that is not NDGA or and NDGA derivative.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

This argument is unpersuasive. The administration of NDGA or an NDGA derivative in combination with an antineoplastic agent *is but one embodiment of the invention disclosed by Howell et al.* In fact, the abstract and col.5, l.10-41 of Howell et al. explicitly and unequivocally discloses the administration of a composition that contains NDGA or a disclosed analog thereof in combination with a pharmaceutically acceptable vehicle, which constitutes a *clear teaching* that Howell et al. contemplated the administration of the NDGA compound to a patient for treating a solid tumor or hematological malignancy (i.e., in this case, leukemia) *in the absence of the administration of any other elements and/or the execution of any other steps (i.e., such as administering an additional agent) to achieve the disclosed therapeutic objective and therefore, meets the "consisting essentially of" language as recited in the instant claims*. Applicant's attempts to focus on other parts of the reference and examples in the reference that allegedly teach combination therapy is unpersuasive because (1) it fails to consider the sections cited by the Examiner that clearly support the administration of the NDGA compound in the absence of other compounds and, thus, meet the "consisting essentially of" requirement of the instant claims and (2) restricts his consideration of the reference only to but one embodiment of the teachings without considering the teachings of the reference *as a whole*. Attempts to focus on a preferred or disclosed embodiment of a reference without considering the full scope of teachings providing by said reference is unimpressive.

Moreover, even if, *arguendo*, Howell et al. did not explicitly teach an embodiment of the invention wherein the NDGA compound was *the only compound to be administered* (which the Examiner

does not concede), Howell et al. clearly teaches that, if an antineoplastic agent is used in combination with the NDGA compound, that the antineoplastic or cytotoxic agent is administered in combination *before, together and/or after* the NDGA or NDGA analog compound. Accordingly, the teaching that the disclosed combination therapy of the NDGA or NDGA analog compound and the antineoplastic agent *at two different times* (i.e., either before or after) meets Applicant's instantly claimed requirement of "consisting essentially of" providing a composition "consisting essentially of" an effective amount of the claimed compound. This is because Howell et al. clearly, explicitly and unequivocally teaches that the antineoplastic or cytotoxic agent and the NDGA or NDGA analog compound may be administered non-simultaneously. As a result of this disclosure, the teachings of Howell et al. expressly provide for the administration of the NDGA compound *separately from the antineoplastic or cytotoxic component* (i.e., thus, administered at a point in time *in the absence of* the antineoplastic or cytotoxic agent) and, thus, constitutes an embodiment wherein the NDGA compound is the sole component administered to a patient (to be followed by an antineoplastic or cytotoxic agent at later time) with the intent to treat a solid tumor or hematological malignancy (i.e., leukemia). In other words, the instant claims require the administration of NDGA excluding the concomitant administration of other elements that would materially alter the basic and novel characteristics of the invention. Again, this is clearly met by Howell et al. because (1) the reference explicitly teaches an embodiment wherein NDGA is the only agent administered (see preceding paragraph) and (2) the reference also explicitly discloses the administration of NDGA at a different time (i.e., *non-simultaneous*) from the antineoplastic or cytotoxic agent and, thus, is clearly a step of administration *in the absence of* the antineoplastic or cytotoxic agent, which, in Applicant's opinion, is allegedly an element that is excluded from the instant claims. Accordingly, the rejection remains proper.

For these reasons *supra*, and those previously made of record at p.3-7 of the Office Action dated October 3, 2008, rejection of claims 9-10, 15, and 18-20 remains proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10, 15, 18-20 and 32-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (U.S. Patent No. 5,541,232; 1996), already of record, for the reasons of record set forth at p.7-11 of the previous Office Action dated October 3, 2008, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Howell et al. requires the administration of at least one additional chemotherapeutic agent.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

This argument is unpersuasive. The administration of NDGA or an NDGA derivative in combination with an antineoplastic agent *is but one embodiment of the invention disclosed by Howell et al.* In fact, the abstract and col.5, l.10-41 of Howell et al. explicitly and unequivocally discloses the

administration of a composition that contains NDGA or a disclosed analog thereof in combination with a pharmaceutically acceptable vehicle, which constitutes a *clear teaching* that Howell et al. contemplated the administration of the NDGA compound to a patient for treating a solid tumor or hematological malignancy (i.e., in this case, leukemia) *in the absence of the administration of any other elements and/or the execution of any other steps (i.e., administration of an additional agent) to achieve the disclosed therapeutic objective and therefore, meets the "consisting essentially of" language as recited in the instant claims*. Applicant's attempts to focus on other parts of the reference and examples in the reference that allegedly teach combination therapy is unpersuasive because (1) it fails to consider the sections cited by the Examiner that clearly support the administration of the NDGA compound in the absence of other compounds and, thus, meet the "consisting essentially of" requirement of the instant claims and (2) restricts his consideration of the reference only to but one embodiment of the teachings without considering the teachings of the reference *as a whole*. Attempts to focus on a preferred or disclosed embodiment of a reference without considering the full scope of teachings providing by said reference is unimpressive.

Moreover, even if, *arguendo*, Howell et al. did not explicitly teach an embodiment of the invention wherein the NDGA compound was *the only compound to be administered* (which the Examiner does not concede), Howell et al. clearly teaches that, if an antineoplastic agent is used in combination with the NDGA compound, that the antineoplastic or cytotoxic agent is administered in combination *before, together and/or after* the NDGA or NDGA analog compound. Accordingly, the teaching that the disclosed combination therapy of the NDGA or NDGA analog compound and the antineoplastic agent *at two different times* (i.e., either before or after) meets Applicant's instantly claimed requirement of "consisting essentially of" providing a composition "consisting essentially of" an effective amount of the claimed compound. This is because Howell et al. clearly, explicitly and unequivocally teaches that the antineoplastic or cytotoxic agent and the NDGA or NDGA analog compound may be administered non-

simultaneously. As a result of this disclosure, the teachings of Howell et al. expressly provide for the administration of the NDGA compound *separately from the antineoplastic or cytotoxic component* (i.e., thus, administered at a point in time *in the absence of* the antineoplastic or cytotoxic agent) and, thus, constitutes an embodiment wherein the NDGA compound is the sole component administered to a patient (to be followed by an antineoplastic or cytotoxic agent at later time) with the intent to treat a solid tumor or hematological malignancy (i.e., leukemia). In other words, the instant claims require the *administration* of NDGA excluding the concomitant administration of other elements that would materially alter the basic and novel characteristics of the invention. Again, this is clearly met by Howell et al. because (1) the reference explicitly teaches an embodiment wherein NDGA is the only agent administered (see preceding paragraph) and (2) the reference also explicitly discloses the administration of NDGA at a different time (i.e., *non-simultaneous*) from the antineoplastic or cytotoxic agent and, thus, is clearly a step of administration *in the absence of* the antineoplastic or cytotoxic agent, which, in Applicant's opinion, is allegedly an element that is excluded from the instant claims. Accordingly, the rejection remains proper.

For these reasons *supra*, and those previously made of record at p.7-11 of the Office Action dated October 3, 2008, rejection of claims 9-10, 15, 18-20 and 32-33 remains proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10, 15, 18-20 and 32-33 remain provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 24-26, 30-32, 35, 39-50, 54-62 and 64-72 of U.S. Patent Application No. 11/284,111, already of record, for the reasons of record set forth at p.11-12 of the previous Office Action dated October 3, 2008, of which said reasons are herein incorporated by reference.

Applicant requests to defer filing a Terminal Disclaimer until allowable subject matter has been indicated.

In view of the fact that allowable subject matter has not yet been identified in the instant case, and further in view of the fact that Applicant has failed to file a Terminal Disclaimer over the cited copending application(s) and also that Applicant has failed to present any arguments or remarks directed to the propriety of the rejection set forth *supra*, the provisional rejection made under the judicially created doctrine of obviousness-type double patenting remains proper and is **maintained**.

Conclusion

Rejection of claims 9-10, 15, 18-20 and 32-33 remains proper.

Claims 34-37 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the

mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

June 23, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614